

**REMARKS**

The foregoing amendments and following remarks are presented in addition to the amendments and remarks submitted with the Amendment filed May 12, 2008.

**Claim Amendments**

Claim 16 has been amended to replace “a compound to be tested” with “a test compound”. Additionally, the phrase “caused by contact of human peripheral blood mononuclear cells with a lipopolysaccharide” has been replaced with “in the presence of human peripheral blood mononuclear cells and a lipopolysaccharide”. These amendments are clearly supported by the previous claim language, and are merely made to aid in the Examiner’s understanding of the claim language.

Claim 16 has further been amended to reinsert the phrase “renal glomerular lesions”, which was deleted in the Amendment filed May 12, 2008. Support for this amendment is clearly found in original claim 16.

Changes of an editorial nature have been made to claim 41, in order to better comply with U.S. practice.

Additionally, new claim 44 has been amended to narrow the target disease recited in claim 16.

No new matter has been added to the application by the above-amendments.

**Rejection Under 35 U.S.C. § 112, First Paragraph**

Please see the remarks set forth on pages 6 and 7 of the Amendment filed May 12, 2008.

**Rejection Under 35 U.S.C. § 102(b)**

In view of the reinsertion of the language “renal glomerular lesions” into claim 16, the comments set forth in the first paragraph on page 8 of the Amendment filed May 12, 2008 are now applicable to new claim 44, rather than claim 16.

Please see the following Supplemental Remarks for independent claim 16, and all of the claims dependent thereon.

Supplemental Remarks

On page 7 of the Office Action, the Examiner interprets claim 16 in light of the specification as a method for screening a compound that requires the step of measuring a promoting action caused by the contact of human peripheral blood mononuclear cells with lipopolysaccharide. The Examiner asserts that the recitation “to be tested on the induction of regeneration-promoting CD11b<sup>+</sup>CD2<sup>+</sup> macrophages and regulator CD2<sup>-</sup>CD4<sup>+</sup> T lymphocytes” has been disregarded as a possible step to be taken in the future.

Initially, Applicant respectfully asserts that the Examiner has mischaracterized Applicant’s claim. Specifically, the claim requires a method for screening a compound . . . comprising measuring a promoting action of a compound on the induction of regeneration-promoting CD11b<sup>+</sup>CD2<sup>+</sup> macrophages and regulatory CD2<sup>-</sup>CD4<sup>+</sup> T lymphocytes”. Applicant respectfully asserts that this is clear from the claim language. However, in order to expedite prosecution, Applicant has amended independent claim 16 to recite “a test compound”, thus clearly indicating that the claimed method is a method for screening a compound, comprising measuring a promoting action of a test compound on the induction of regeneration-promoting CD11b<sup>+</sup>CD2<sup>+</sup> macrophages and regulatory CD2<sup>-</sup>CD4<sup>+</sup> T lymphocytes, in the presence of human peripheral blood mononuclear cells and a lipopolysaccharide.

The reference cited by the Examiner fails to teach or suggest this recited method. In fact, the Examiner has not even discussed measuring a promoting action of a compound on the induction of regeneration-promoting CD11b<sup>+</sup>CD2<sup>+</sup> macrophages and regulatory CD2<sup>-</sup>CD4<sup>+</sup> T lymphocytes, as recited in Applicant’s independent claim 16. Thus, the cited reference does not teach each and every limitation of Applicant’s claims and accordingly fails to anticipate Applicant’s amended claims.

Additionally, as stated in the remarks submitted May 12, 2008, the cited reference

does not teach or suggest a method for screening a compound which is able to mitigate or treat lesions of pancreatic islets of Langerhans or epidermal lesions, as recited in

Applicant's claim 44. MPEP 2173.05(g) states that a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.

A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step. Therefore, the functional limitation that Applicant's claimed method screens for a compound which is capable of mitigating or treating lesions of pancreatic islets of Langerhans or epidermal lesions must be considered when determining patentability.

#### **Conclusion**

Therefore, in view of the foregoing amendments and remarks, as well as the amendments and remarks previously submitted on May 12, 2008, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

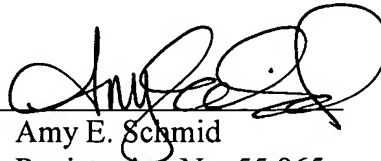
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If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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